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09/649,108	08/28/2000	Licping Chen	07039-220001	7772

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EXAMINER

ROARK, JESSICA H

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/649,108

Applicant(s)

CHEN, LIEPING

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2002 and 20 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8 and 10-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 9, 49 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 10/28/02, is acknowledged.

Claims 6, 7 and 9 have been amended.

Claims 49 and 50 have been added.

*Claims 1-50 are pending.*

2. Claims 1-5, 8 and 10-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

*Claims 6-7, 9 and 49-50 are under consideration in the instant application.*

3. The formal drawings submitted 11/20/02 have been approved by the Draftsman.

4. This Office Action will be in response to applicant's arguments, filed 10/28/02 (Paper No. 18).

The rejections of record can be found in the previous Office Action (Paper No. 15).

It is noted that New Grounds of Rejection are set forth herein.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

6. Applicant's amendment, filed 10/28/02, in conjunction with the arguments presented therein regarding the definition of "ability to co-stimulate a T cell", has obviated the previous rejection of claims 6-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement.

7. Applicant's amendment, filed 10/28/02, in conjunction with the arguments presented therein regarding the definition of "ability to co-stimulate a T cell", has obviated the previous rejection of claims 6-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, written description.

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8. Claims 6-7, 9 and 49-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons:*

Applicant's amendment asserts that no New Matter has been added and points to the specification at page 16, lines 6-8 for support for the newly added limitation regarding the stringent hybridization conditions, including a wash at "65 C". However, the specification does not appear to provide an adequate written description of a wash at "65 C". The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

The instant language now recites a species when only a range was disclosed.

In Purdue Pharma L.P. v Faulding Inc., 56 USPQ2d 1481, 1486 (CA FC 2000) the Court noted with respect to In re Ruschig 379 F.2d 990, 154 USPQ 118 (CCPA 1967) that "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say 'here is my invention.' In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure. See [In re Ruschig] at 994-95, 154 USPQ at 122; Fujikawa, 93 F.3d at 1570-71, 39 USPQ2d at 1905; Martin v. Mayer, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337(Fed. Cir. 1987) ("It is 'not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure. ... Rather, it is a question whether the application necessarily discloses that particular device.'") (quoting Jepson v. Coleman, 314 F.2d 533, 536, 136 USPQ 647, 649-50(CCPA 1963))".

Applicant is required to cancel the New Matter in the response to this Office Action to clearly point out the written support for the instant limitations.

Alternatively, Applicant is invited to amend the claim to recite the range disclosed on page 16 at line 8 to obviate this rejection.

9. Applicant's amendment, filed 10/28/02, in conjunction with the arguments presented therein regarding the definition of "ability to co-stimulate a T cell", has obviated the previous rejection of claims 6-7 and 9 are rejected under 35 U.S.C. 112, second paragraph.

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

11. Applicant's amendment, filed 10/28/02, has obviated the previous rejection of claim 6 under 35 U.S.C. 102(e) as being anticipated by Ostrand-Rosenberg et al. (U.S. Pat. No. 5,858,776, of record).

12. Claims 6-7, 9 and 49-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Freeman et al. (US2002/0102651, see entire document).

Freeman et al teach the human B7-4 polypeptide of SEQ ID NO:4 encoded by SEQ ID NO:1 (see entire document, including sequence listing and Figures). SEQ ID NO:4 is taught at paragraphs 313-315 to costimulate T cells. The complement of the nucleic acid of SEQ ID NO:1 of Freeman et al. would hybridize to SEQ ID NO:1 of Freeman et al. after a wash at 65 degrees C in a buffer containing 0.2x SSC and 0.1% SDS; therefore SEQ ID NO:1 itself is a nucleic acid that hybridizes as recited in instant claim 1 and encodes a polypeptide which co-stimulates a T cell.

SEQ ID NO:4 of Freeman et al. is a polypeptide of 290 amino acids that is identical to instant SEQ ID NO:1 over its full length. Therefore, the B7-4 polypeptide of Freeman et al. is a polypeptide comprising: amino acid residue 23 (or amino acid residue 30) to amino acid residue 290 of instant SEQ ID NO:1; SEQ ID NO:1 itself; and SEQ ID NO:10 (the extracellular domain of SEQ ID NO:1).

Freeman et al. also teach polypeptides which differ from the B7-4 polypeptide set forth in SEQ ID NO:4 of Freeman et al. by one or more conservative amino acid substitutions (see e.g., paragraphs 88-93)

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the \*\*\*\*.

The reference teachings thus anticipate the instant claimed invention.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Holtzman et al. (US2002/0055139), see in particular pages 1-8, 11, 37-42 and 60, as well as SEQ ID NOS:40 and 41 and Figures 50-55 with respect to references to TANGO 509.

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14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.  
Patent Examiner  
Technology Center 1600  
January 13, 2003

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1/14/03